Remarks/Arguments

A. Summary of the claims

Claims 1-5 and 7-8 are canceled, and claims 6 and 9 are amended. Support for the amendments can be found throughout the specification and claims as originally filed. For instance, the subject-matter of original claims 7 and 8 has been inserted into claim 6, and the phrase "suspected of causing teratogenicity" finds support on page 3, paragraph [0012]. Claim 9 now recites "wherein the at least one vitamin is pyridoxine HCl and wherein the at least one active ingredient further comprises doxylamine succinate", and support can be found at page 3, paragraph [0012].

Claims 6 and 9 are pending in this case.

B. Election/Restrictions

The Examiner has acknowledged the election without traverse of Group I.

C. The Indefiniteness Rejection Is Overcome

Claims 5 and 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner contends that it is unclear whether "at least one active ingredient" is either pyridoxine HCl or doxylamine succinate alone, or both drugs in combination.

Applicant disagrees. The claims, prior to any amendment made above, were definite and satisfied the requirements under § 112, second paragraph. A person of skill in the art could understand these claims when read in light of the specification. For example, Diclectin™ contains both pyridoxine HCl and doxylamine succinate in combination.

However, in an effort to further the prosecution and secure prompt allowance, the claims have been amended to address the Examiner's concern. As indicated above, claim 5 is canceled.

Claim 9 recites "wherein the at least one vitamin is pyridoxine HCl and wherein the at least one active ingredient further comprises doxylamine succinate."

In view of the above, Applicant requests that the present indefiniteness rejection of claims 5 and 9 be withdrawn.

D. The Anticipation Rejection Is Overcome

Claim 6 is rejected under 35 U.S.C. § 102 as being anticipated by Orifer F Prenatal Vitamin Supplement (September 25, 1996).

Applicant disagrees. Claim 6, prior to any amendment made above, was not anticipated by the cited reference. However, in an effort to further the prosecution and secure prompt allowance, claim 6 has been amended to specifically designate a pharmaceutical tablet with several features, including that of the pregnancy-friendly indicia being applied to the surface of the tablet, which is clearly not disclosed in Orifer F—a fact acknowledged by the Examiner. Action at page 4 ("ORIFER F does not explicitly show the pregnancy friendly indicia as being on the dosage form itself").

In view of the above, Applicant respectfully requests that the present anticipation rejection be withdrawn.

E. The Obviousness Rejections Are Overcome

1. The Obviousness Rejections of Claims 1-9 over Orifer F in view of WO 97/48384, and *vice versa*, Are Overcome

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as being obvious over Orifer F in view of WO 97/48384. Claims 1-9 are also rejected under 35 U.S.C. § 103(a) as being obvious over WO 97/48384 in view of Orifer F.

Applicant disagrees with these rejections. The claims, prior to any amendment made above, were not rendered obvious by the cited references. However, in an effort to further the

prosecution and secure prompt allowance, claims 1-5 have been canceled and claim 6 amended to specifically designate *"a pharmaceutical tablet comprising at least one active ingredient suspected of causing teratogenicity and destined for administration to pregnant women, wherein the at least one active ingredient comprises at least one vitamin, said pharmaceutical tablet bearing a pregnancy-friendly indicia adapted to graphically confirm the non-teratogenic aspect of the pharmaceutical tablet, said indicia being in the shape of a graphical illustration of a pregnant woman applied to the tablet surface"*.

Claim 6 not obvious over the cited references for at least the reasons explained in the following subsections.

a. A Prima Facie Case of Obviousness Has Not Been Established

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *Manual of Patent Examining Procedure* § 2142. All three elements are missing.

For instance, Orifer F appears to disclose a representation of a pregnant woman on the packaging of a prenatal vitamin. As *acknowledged* by the Examiner, Orifer F does not show the pregnancy friendly indicia on the dosage form itself. Action at page 4.

Applicant respectfully submits that nothing in the Orifer publication teaches or suggests any practical effect of graphical indicia representing a pregnant woman on a packaging.

In support, Applicant submits a declaration from Dr. Gideon Koren of The Hospital for Sick Children, Toronto (Koren Declaration), a copy of which is attached at Appendix 1.

Dr. Koren provides his opinion that the presently claimed invention is not obvious in view of the Orifer publication. Indeed, the Orifer publication does not use any pregnancy-related indicia on the dosage form itself and fails to provide any teachings as to diminishing perception of teratogenic risk or improving patient compliance.

WO 97/48384 merely discloses the general principle of marking the surface of solid rapidly disintegrating dosage forms using a non-contact marking technique such as laser imprinting and ink-jet printing.

Applicant submits that nothing in WO 97/48384 teaches or suggests to mark a solid dosage form with a pregnancy friendly indicia. In addition, nothing teaches or suggests any practical effect of any indicia imprinted on a solid dosage form on the perception of the teratogenic risk, or even generally in the context of pregnancy.

Applicant submits that a person of skill in the art would not find, in any of the cited references, or in the knowledge generally available to him or her, any suggestion or motivation to modify Orifer F or to combine its teachings with those of WO 97/48384, or vice versa, to obtain Applicant's claimed invention. For example, neither of the cited references disclose or suggest the technical problem of the present invention, namely diminishing the perception of the teratogenic risk and improving compliance among pregnant women, as generally stated in the present application on page 5, paragraphs [0018] to [0020]. This is strong evidence of non-obviousness. *See* MPEP § 2143.01 ("The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.") (underlines in original). Further, Applicant respectfully notes that "obvious to try" is not the appropriate standard under 35 U.S.C. § 103. *The Gillette Co. v.*

S.C. Johnson & Son, Inc., 919 F.2d 720 (Fed. Cir. 1990) (noting that "obvious to try" is not to be equated with obviousness under 35 U.S.C. 103).

In addition, since nothing in the Orifer publication teaches or suggests any practical effect of graphical indicia representing a pregnant woman on a packaging, and since nothing in WO 97/48384 teaches or suggests any practical effect of any indicia imprinted on a solid dosage form on the perception of the teratogenic risk, or even generally in the context of pregnancy, there is no reasonable expectation of success in a combination of these two documents. This is further evidence of non-obviousness. *See* MPEP § 2143.02.

It is clear that the cited references fail to teach or suggest a pharmaceutical tablet bearing pregnancy-friendly indicia adapted to graphically confirm the non-teratogenic aspect of the pharmaceutical tablet. Thus the combination of the cited references do not teach or suggest all of the claim limitations, and the present obviousness rejection cannot be maintained. MPEP § 2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art").

Applicant therefore respectfully submits that the three basic criteria for establishing a *prima facie* case of obviousness are missing (MPEP § 2142), and that the present obviousness objections are overcome.

b. Secondary Considerations of Non-Obviousness Are Present

Unexpected results

Applicant also notes that the pharmaceutical tablets bearing pregnancy-friendly indicia as defined in claim 6 provided surprising and unexpected results. The present application clearly demonstrates (Example 2) the clinically significant and statistically reliable effect of placing the graphical representation of a pregnant woman on the surface of a tablet, as compared to plain

tablets without any indicia. This is further evidence of non-obviousness of the claims on file. MPEP 716.02(a), (b) and (c). The effect is observed on a patient's perception of the teratogenic risk, which in turn influences patient's compliance with a prescribed drug regimen.

Commercial success

Moreover, Applicant respectfully submits that the sales of Diclectin™ significantly and unexpectedly increased in the year that followed the application of the pregnant woman indicia on the commercialized Diclectin™ tablets. This is explained in the Declaration by Eric Gervais who is a named inventor on this application and an employee of the Assignee, Duchesnay, Inc. A copy of the Declaration is attached at Appendix 2. In brief, these sales increases observed are directly attributed to the claimed application of the pregnant woman indicia on the pharmaceutical tablets since nothing else was modified in the medicament itself, or in the sales and marketing of the drug. Gervais Declaration at ¶¶ 11-12. In particular, a significant increase of the sales was observed in several regions of Canada, even where Duchesnay had absolutely no medical representative. *Id.* at ¶¶ 13-14. The indicia thus most probably caused greater patient compliance as seen in a vast increase in prescriptions. Once again, no other factors changed. The result was thus attributed to the indicia, and was clearly unpredictable. This unexpected commercial success, commensurate with and derived from the claimed indicia, constitutes further evidence of the non-obviousness of the present claims. MPEP 716.03.

In view of the above, Applicant respectfully requests that the present obviousness rejections be withdrawn.

2. The Obviousness Rejection of Claims 5-9 over Gervais in view of Orifer F and WO 97/48384 Are Overcome

Claims 5-9 are rejected under 35 U.S.C. § 103(a) as being obvious over Gervais (US 6,340,695) in view of Orifer F in view of WO 97/48384.

Applicant disagrees. These claims, prior to any amendment made above, were not rendered obvious by the cited references. However, in an effort to further the prosecution and secure prompt allowance, claims 1-5 have been canceled and claim 6 and 9 amended as specified above.

Gervais discloses a rapid onset enterically-coated formulation comprising as active ingredients pyridoxine HCl and doxylamine succinate, such combination being known for the treatment of nausea and vomiting in pregnancy.

Applicant submits that nothing in Gervais teaches or suggests to mark the formulation with a pregnancy friendly indicia or to diminish the perception of the teratogenic risk in anyway. There is therefore no motivation to combine the formulation taught by Gervais with Orifer F in view of WO 97/48384.

In addition, Applicant submits that the arguments stated above with regard to an improbable combination of Orifer F and WO 97/48384 equally apply here.

Thus, Applicant respectfully requests that the present obviousness rejection be withdrawn.

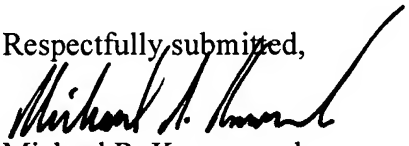
F. Conclusion

Applicant believes that this is a complete response to the Office Action mailed June 13, 2006. The present claims are in a condition for allowance, and such favorable action is requested.

As noted above, a petition for a one-month extension of time is being filed concurrently with this response. If the payment for the one-month extension fee is inadequate or inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/GOUD:031US.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3030 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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